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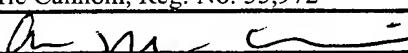
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|  |   |                        |                |
|--|---|------------------------|----------------|
|  |   | Application Number     | 10/057,629     |
|  |   | Filing Date            | 01/25/2002     |
|  |   | First Named Inventor   | Harry R. Davis |
|  |   | Art Unit               | 1614           |
|  |   | Examiner Name          | To Be Assigned |
| Total Number of Pages in This Submission | 5 | Attorney Docket Number | CV01382K       |

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| ENCLOSURES (Check all that apply)  |   |  |
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| <input type="checkbox"/> Fee Transmittal Form                                | <input type="checkbox"/> Drawing(s)                                       | <input type="checkbox"/> After Allowance Communication to Group                            |
| <input type="checkbox"/> Fee Attached  | <input type="checkbox"/> Licensing-related Papers                         | <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences        |
| <input type="checkbox"/> Amendment/Reply                                     | <input type="checkbox"/> Petition   | <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) |
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| <input type="checkbox"/> Extension of Time Request                           | <input type="checkbox"/> Change of Correspondence Address                 | <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):            |
| <input type="checkbox"/> Express Abandonment Request                         | <input type="checkbox"/> Terminal Disclaimer                              | Form PTO-1449 (1 pg. in dup.);   |
| <input checked="" type="checkbox"/> Information Disclosure Statement         | <input type="checkbox"/> Request for Refund                               | References (13); Post Card   |
| <input type="checkbox"/> Certified Copy of Priority Document(s)              | <input type="checkbox"/> CD, Number of CD(s)                              |  |
| <input type="checkbox"/> Response to Missing Parts/ Incomplete Application   |   |  |
| <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53 |   |  |
| Remarks  |   |  |

## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

|                    |   |
|--------------------|---|
| Firm or Individual | Ann Marie Cannon, Reg. No. 35,972   |
| Signature          |  |
| Date               | April 28, 2003  |

## CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, Washington, DC 20231 on this date: April 28, 2003

|                  |   |
|------------------|---|
| Typed or printed | Ann Marie Cannon  |
| Signature        |  |
| Date             | April 28, 2003  |

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

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PATENT CASE CV01382K

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:  
**Harry R. Davis**

For:  
**USE OF SUBSTITUTED AZETIDINONE  
COMPOUNDS FOR THE TREATMENT OF  
SITOSTEROLEMIA**

Serial No.: **10/057,629**

Filed: **January 25, 2002**

Assistant Commissioner of Patents  
Washington, D.C. 20231

Examiner: To Be Assigned  
Group Art Unit: 1614  
Attorney Docket No.: CV01382K

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

Applicants respectfully request that the following be considered and made of record, as well as the documents listed on the accompanying PTO Form 1449.

A research study was initiated on April 17, 1997 in the United States in which patients were administered capsules of the formulations of Exhibits A, B or C. Copies of the formulation Exhibits A, B and C and the informed consent form for the study (Exhibit 1) are submitted herewith for the Examiner's consideration.

A research study was initiated on October 21, 1997 in the United States in which patients were administered tablets of the formulations of Exhibits D or E or capsules of formulation of Exhibit C. Copies of the formulation Exhibits C, D and E and the informed consent for the study (Exhibit 2) are submitted herewith for the Examiner's consideration.

A research study was initiated on November 5, 1998 in the United States in which patients were administered tablets of formulations of Exhibits D, F, G or H. Copies of the formulation Exhibits D, F, G and H and the informed consent for the study (Exhibit 3) are submitted herewith for the Examiner's consideration.

A research study was initiated on April 20, 1999 in the United States in which patients were administered tablets of the formulation of Exhibit D, optionally in coadministration with digoxin. Copies of the formulation Exhibit D and the informed consent for the study (Exhibit 4) are submitted herewith for the Examiner's consideration.

A research study was initiated on August 27, 1999 in the United States in which patients were administered tablets of the formulation of Exhibit D optionally in coadministration with Gemfibrozil 600mg tablets. Copies of the formulation Exhibit D and the informed consent for the study (Exhibit 5) are submitted herewith for the Examiner's consideration.

In the Informed Consents accompanying the above research studies, Schering's active pharmaceutical ingredient, i.e., ezetimibe, was identified as "SCH 58235" and as an "experimental drug which inhibits the absorption of cholesterol". It was not identified by its chemical name, generic name or by its chemical formula.

It is our belief that these studies do not constitute prior public uses. Nevertheless, this information is being disclosed in accordance with 37 C.F.R. Section 1.56 out of an abundance of caution.

The Commissioner is authorized to charge Deposit Account No. 19-0365 for any additional fees deemed necessary for consideration and entry of this Information Disclosure Statement into the file record.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to Assistant Commissioner for Patents, Washington D.C., 20231 on 4/28/03

Respectfully submitted

Ann Marie Cannon  
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Registered Representative  
A. Cannon 4/28/03  
Signature Date

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